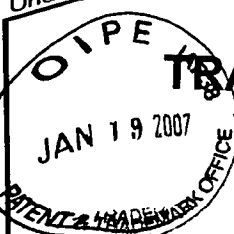


IN 2621

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/571,012
Filing Date	March 8, 2006
First Named Inventor	Frank Cuttitta
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	31978-228047

## ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> <b>Fee Transmittal Form</b> <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> <b>Information Disclosure Statement with PTO/SB/08A ( docs.)</b> <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> <b>Other Enclosures (please identify below):</b> <b>International Search Report</b>
<div>Remarks</div>		

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	VENABLE LLP		
Signature	<i>Nancy Axelrod</i>		
Printed name	Nancy J. Axelrod		
Date	1/19/07	Reg. No.	44,014

Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004.  
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).**FEE TRANSMITTAL**  
**For FY 2005**☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 0.00**Complete if Known**

Application Number	10/571,012
Filing Date	March 8, 2006
First Named Inventor	Frank Cuttitta
Examiner Name	Not Yet Assigned
Art Unit	Not Yet Assigned
Attorney Docket No.	31978-228047

**METHOD OF PAYMENT** (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account Deposit Account Number: 22-0261 Deposit Account Name: Venable LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	<u>Small Entity</u> Fee (\$)	Fee (\$)	<u>Small Entity</u> Fee (\$)	Fee (\$)	<u>Small Entity</u> Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	<u>Small Entity</u> Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims    Extra Claims    Fee (\$)    Fee Paid (\$)

\_\_\_\_\_ - 20 = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims    Extra Claims    Fee (\$)    Fee Paid (\$)

\_\_\_\_\_ - 3 = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of independent claims paid for, if greater than 3.

**Multiple Dependent Claims**

Fee (\$)    Fee Paid (\$)

\_\_\_\_\_

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets    Extra Sheets    Number of each additional 50 or fraction thereof    Fee (\$)    Fee Paid (\$)

\_\_\_\_\_ - 100 = \_\_\_\_\_ / 50 \_\_\_\_\_ (round up to a whole number) x \_\_\_\_\_ = \_\_\_\_\_

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): \_\_\_\_\_

Fees Paid (\$)**SUBMITTED BY**

Signature	<u>Nancy Axelrod</u>	Registration No. (Attorney/Agent)	44,014	Telephone	(202) 344-4000
Name (Print/Type)	Nancy J. Axelrod	Date	<u>1/19/07</u>		



Docket No.: 31978-228047  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Frank CUTTITTA et al.

Art Unit: Not Yet Assigned

Application No: 10/571,012

Examiner: Not Yet Assigned

Confirmation No: Not Yet Assigned

Atty. Docket No: 31978-228047

Filed: March 8, 2006

Customer No:

For: NON PEPTIDE AGONISTS AND  
ANTAGONISTS OF ADRENOMEDULLIN  
AND GASTRIC RELEASING PEPTIDE

**26694**  
PATENT TRADEMARK OFFICE

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the documents be made of record therein and appear on any patent to issue therefrom. Copies of documents **BA**, **CA-CK**, and **CA16** are enclosed herewith.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant submits herewith copies of foreign patents and non-patent literature in accordance with 37 CFR 1.98(a)(2).

Copies of documents **BB-BG** and **CA1-CA15** are not being provided since copies were previously provided by WIPO under an exchange program between the PTO, the EPO and the JPO.

The Examiner is directed to the corresponding International Application No. PCT/US2004/029293, filed September 8, 2004, for copies of documents **BB-BG** and **CA1-CA15**.

A concise explanation of relevance of the items listed on form PTO/SB/08 is in the form of a International Search Report (document **CA16**) issued in a counterpart application, which refers to the relevant portions of the documents. A copy of the International Search Report is enclosed herewith.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 22-0261, under Order No. 31978-228047. A Fee Transmittal is enclosed.

Dated: Jan. 19, 2007

Respectfully submitted,

By Nancy Axelrod

Nancy J. Axelrod

Registration No.: 44,014

VENABLE LLP

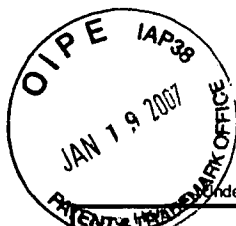
P.O. Box 34385

Washington, DC 20043-9998

(202) 344-4000

(202) 344-8300 (Fax)

Attorney/Agent For Applicant



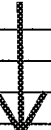
PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031  
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/571,012	
			Filing Date	March 8, 2006	
			First Named Inventor	Frank Cuttitta	
			Art Unit	Not Yet Assigned	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	3	Attorney Docket Number	31978-228047

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
/A.P./	AA	US-20020019347 A1	02-14-2002	KARL GUEGLER ET AL	
	AB	US-20020055615 A1	05-09-2002	FRANK CUTTITTA, ET AL.	
	AC	US-20020176819 A1	11-28-2002	HOFFMAN ET AL.	
	AD	US-4,517,188	05-14-1985	LAWSON ET AL.	
	AE	US-5,047,502	09-10-1991	OLIFF ET AL	
	AF	US-5,109,115	04-28-1992	CUTTITTA ET AL..	
	AG	US-5,460,801	10-24-1995	CUTTITTA	
	AH	US-5,834,433	11-10-1998	KRSTENANSKY	
/A.P./	AI	US-5,620,955	04-15-1997	KNIGHT ET AL.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
/A.P./	BA	JP 10-212235	08-11-1998	Nippon Shoji Co. Ltd., published in (1998)		
	BB	EP 0806418	11-12-1997	Nippon Shoji Kaisha Ltd. published (1997)		
	BC	FR 2 241 313 A	03-21-1975	SANDOZ S.A.		
	BD	W0 97/07214 A	02-27-1997	UNSWORTH ET AL.		
	BE	W0 99/05299 A	02-04-1999	TRUSTEES OF BOSTON UNIVERSITY		
	BF	EP 0 806 418 A	11-12-1997	NIPPON SHOJI KAISHA, LIMITED		
/A.P./	BG	W0 00/30630 A	06-02-2000	LINDEN BIOTECHNOLOGY, INC. ET AL.		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/A.P./	CA	CUTTITTA et al., "Identification of Peptide Growth Factors that Regulate Human Tumor Proliferation," Progress report in the CRISP web site, of Grant No.: 1Z01SC000173-10 (2002)	
/A.P./	CB	COPPOCK et al., "Rat-2 fibroblasts express specific adrenomedullin receptors, but not calcitonon-gene-related-peptide receptors, which mediate increased intracellular cAMP and inhibit mitogen-activated protein kinase activity," Biochem J. 338, 15-22 (1999)	
/A.P./	CC	DRAOUI, Dissertation, George Washington University (1993)	
/A.P./	CD	GANGULY et al. "Synthesis of Pyrimidine Derivative; Part V – Synthesis of Some 2-Methylthio-(or 2-amino)-6-(substituted)-aminopyrimidines," Indian Journal of Chemistry.; 1, (8) 364 (1963)	

Examiner Signature	/Anna Pagonakis/	Date Considered	02/08/2010
-----------------------	------------------	--------------------	------------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/571,012
				Filing Date	March 8, 2006
				First Named Inventor	Frank Cuttitta
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	31978-228047

/A.P./	CE	GIBSON et al. "Specific inhibitors in vitamin biosynthesis. Part 10. Synthesis of 7-and 8-substituted 7-deazaguanines," Journal of the American Chemical Society, Perkin Transaction 1: Organic and Bio-Organic Chemistry 18, 3025-30325 (1998)	
/A.P./	CF	HEIMBROOK et al. "Gastrin Releasing Peptide Antagonists with Improved Potency And Stability", J. Med. Chem. 34, 2102-2107 (1991)	
/A.P./	CG	ISHIZAKA et al. "Adrenomedullin Stimulates Cyclic AMP Formation in rat Vascular smooth muscle cells", Biochem. Biophys. Res. Comm. 200, 642-646 (1994)	
/A.P./	CH	ISUMI et al. "Adrenomedullin Production in Fibroblasts: Its Possible Function as a Growth Regulator of Swiss 3T3 Cells", Endocrinology 139. 2552-2563 (1998)	
/A.P./	CI	O'BRIEN, DARRELL E. et al. "Synthesis and Antitumor Activity of 9-Substituted Nitrogen Mustard Derivatives of 6-Alkylthiopurines," Journal of Medicinal Chemistry 8, 182-7 (1965)	
/A.P./	CJ	PFICIDERER et al. "Synthese von 2-Amino-4-alkoxy-7-oxo-dropteridinen," Chemische Berichte 94, 2708-21 (including an English Abstract prepared by CAPLUS) (1961)	✓
/A.P./	CK	SCHALLY et al. "Hypothalamic Hormones and Cancer", Front. Neuroendocrinol. 22, 248-91 (2001)	
/A.P./	CA1	AMIR S M et al: "Polyphloreitin Phosphate an Antagonist Of Thyrotropin Action Evidence for an Interaction with the Hormone rather than the Receptor," Front. Neuroendocrinol 22, vol. 117, no. 3, pages 860-868 (1985)	CC
/A.P./	CA2	ASHWOOD V et al: "Pd 176252-The First High Affinity Non-Peptide Gastrin-Releasing Peptide (Bb2) Receptor Antagonist," Bioorganic & Medicinal Chemistry Letters, Oxford, GB, vol. 8, no. 18, pages 2589-2594 (1998)	
/A.P./	CA3	BAJO et al: "Bombesin Antagonists Inhibit Proangiogenic Factors in Human Experimental Breast Cancers," Br. Journal of Cancer 90, 245-252 (2004)	
/A.P./	CA4	CUTTITTA F et al: "Bombesin-Like Peptides Can Function as Autocrine Growth Factors In Human Small-Cell Lung Cancer," Nature (London), vol. 316, no. 6031, (1985) 823-826	
/A.P./	CA5	DAENIKER, H.U. et al: "Chemotherapeutic studies in the heterocyclic series. XVIII. Polymethlenedi (sydnones) and Polymethylenedi (hydrazines)," Helvetica Chemical Acta, 40. 918-32 pages 920 and 325 (1957)	
/A.P./	CA6	DATABASE CA 'Online! Chemical Abstracts Service, Columbus, Ohio, US; CHERNOV, V.A. et al: "Antiblastomic activity of sydnone imines", retrieved from Database accession no. 1964:406942 (1964) & Doklady Akademii Nauk SSSR, 155 (1), 216-19 Coden: Dankas (1964)	
/A.P./	CA7	EAKIN A E et al., "Comparative Complement Selection in Bacteria Enables screening for lead compounds targeted to a purine salvage enzyme of parasites," Antimicrobial Agents and Chemotherapy, American Society for Microbiology, Vol. 39 no. 3 pages 620-625 (1995)	
/A.P./	CA8	EGUCHI SATORU et al: "Structure-activity relationship of adrenomedullin, a novel vasodilatory peptide, in cultured rat vascular smooth muscle cells," Endocrinology, Baltimore, MD vol. 135, no. 6, pages 2454-2458 (1994)	
/A.P./	CA9	GASPARETTO M et. al: "Identification of compounds that enhance the anti-lymphoma activity of rituximab using flow cytometric high-content screening; Journal Of Immunological Methods, Elsevier Science Publishers B.V., Amsterdam, NL, vol. 292, no. 1-2, pages 59-71 (2004)	
/A.P./	CA10	HEUSER MARKUS et al: "The inhibition of angiogenesis and microcirculation in renal cell carcinoma spheroids by gastrin releasing peptide receptor (GRP-R) antagonism depends on the time of treatment initiation," Journal of Urology, vol. 169, no. 4 Supplement, (2003), page 207, 98 <sup>th</sup> Annual Meeting of the American Urological Association (AUA); Chicago, IL USA: April 26-May 2, 2003	

Examiner Signature	/Anna Pagonakis/	Date Considered	02/08/2010
--------------------	------------------	-----------------	------------

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

3

of

3

**Complete if Known**

Application Number	10/571,012
Filing Date	March 8, 2006
First Named Inventor	Frank Cuttitta
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	31978-228047

/A.P./	CA11	LOOKER, J.H. et al. "1,2,3-Thiadiazoles As Potential Antineoplastic Agents, I. Synthesis Of Novel 4-Monosubstituted And 4,5-Disubstituted Derivatives Physiologically Active Compounds. III. Hydrochlorides Of Amino Esters Of Phenylchohexylglycolic Acids, Of Amides Of Benzilic, Phenylcyclohexyl- And Dicyclohexylglycolic," Journal of Heterocyclic Chemistry, 2 (4), 348-54 (1965)
/A.P./	CA12	MARTINEZ A et al: "Identification Of Vasoactive Nonpeptidic Positive and Negative Modulators of Adrenomedullin using A Neutralizing Antibody-Based Screening Strategy," Endocrinology 2004 United States, vol. 145, no. 8, pages 3858-3865 (2004)
/A.P./	CA13	MURAD S et al: "Structure-Activity Relationship of Minoxidil Analogs as Inhibitors of Lysyl Hydroxylase In Cultured Fibroblasts1," Archives of Biochemistry and Biophysics, New York, US, vol. 292, no. 1, pages 234-238 (1992)
/A.P./	CA14	THOMAS F et al: "Antitumoral Activity Of Bombesin Analogue On Small Cell Lungs Cancer Xenografts Relationship With Bombesin Receptor Expression," Cancer Research, vol. 52, no. 18, pages 4872-4877 (1992)
/A.P./	CA15	TMEJ C et al: "A Combined Hansch/Free-Wilson Approach As Predictive Tool in Qsar Studies on Propafenone-Type Modulators Of Multidrug Resistance," Archiv Der Pharmazie," VCH VERLAGSGESELLSCHAFT MBH, WEINHEIM, DE, vol. 331, no. 7/8, pages 233-240 (1998)
/A.P./	CA16	International Search Report dated 07-01-2005, issued in PCT/US2004/029293

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Anna Pagonakis/	Date Considered	02/08/2010
-----------------------	------------------	--------------------	------------